For Reference Only

MINISTRY OF HEALTH
No.: **6586**/BYT-K2ĐT

Re: Instruction on reporting, recording SAE in clinical trial.

SOCIALIST REPUBLIC OF VIETNAM
Independence - Freedom - Happiness

Hanoi, October 2nd, 2012

To:

- Clinical Trial (main) sites
- Sponsors
- Contract Research Organisations (CROs)

……...

In order to assure the research quality and the safety for subjects participating in the clinical tests carried out in, pursuant to Circular 03/2012/TT-BYT dated 02/02/2012 on Guidance to Clinical Trial, Ministry of Health promulgate **Instruction on Recording, Settling and Reporting Serious Adverse Events (SAE) in Clinical Trial Carried Out in Vietnam** and SAE report form enclosed with this official letter.

Ministry of Health kindly requests clinical trial (main) sites, sponsors and CROs to implement and comply with this Instruction.

This instruction replaces instruction enclosed with official letter no. 558/BYT-K2ĐT dated 13-February-2012.

Thank you for your cooperation.

Recipients:
- As mentioned above (enclosed list);
- Minister (for reporting);
- Director (for reporting);
- Pharma group;
- National ADR Center (for cooperation);
- SMO, CROs;
- Filling: Office, K2DT(2).

BY ORDER OF MINISTER
PP. DIRECTOR OF DEPARTMENT OF SCIENCE AND TRAINING
VICE DIRECTOR

[Seal affixed: Ministry of Health]

[Signature affixed]

Nguyen Ngo Quang

For Reference Only

MINISTRY OF HEALTH

SOCIALIST REPUBLIC OF VIETNAM
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INSTRUCTION

on Recording, Settling and Reporting Serious Adverse Events (SAE) in the Clinical Trials Carried Out in Vietnam

*(Enclosed with the official letter No. **6586** dated October 2nd 2012)*

1. General principle

The settling, recording and reporting of Serious Adverse Events (SAE) in clinical trials must comply with the International and Vietnam instructions on Good Clinical Practice (GCP).

This Instruction is applied to SAEs that happen in the clinical trial sites carried out in Vietnam.

2. Definition and classification

a) *Adverse event (AE)* is any unfavourable medical event or situation in a subject participating in a clinical trial, whether or not considered related to the investigational product. An adverse event can therefore be any adverse sign, symptom, disease or laboratory finding which occurs as the subject participates in the clinical trial, and may or may not relate to investigational product.

b) *Serious Adverse Event (SAE)* is the adverse event that at any dose results in death or is life-threatening, requires inpatient hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability/incapacity, or is a congenital anomaly/birth defect.

c) *Adverse Drug Reaction (ADR)* is an unexpected harmful adverse reaction, which happens on the subject participating in the clinical trial and has causal relationship with investigational product at any dose. For marketed products: ADR is a response to a drug which is noxious and unintended and which occurs

at doses normally used in man for prophylaxis, diagnosis, or therapy of disease or for modification of physiological function.

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d) *Unexpected Adverse Drug Reaction* is an adverse drug reaction of which nature of severity has not been acknowledged in the previous research studies or in current product information.

3. Responsibilities of the Parties in acknowledging, settling and reporting SAEs in the clinical tests carried out in Vietnam

a) *Principal investigator at the research site* is responsible for detecting and settling SAEs to ensure the timeliness and safety for the research subject; monitoring and making full record of information; sending the SAE report to the Sponsor, Institutional Ethics Committee, Evaluation Board on Ethics Issues of the Ministry of Health.

b) *Clinical trial site* is responsible for managing, supervising the detection, settling and monitoring the SAE report at the site to ensure the safety of the research subject.

c) *Institutional Ethics/Scientific Committee* of the trial sites considers and presents professional opinions about SAEs that occurred at the research site and ensures the absolute safety of the research subject.

d) *Sponsor and organisations authorized by sponsor* (organisation, individual having investigational product; contract research organisation, research site monitor organisation) are responsible for:

Coordinating with the principal investigator to report the SAE that occurred at the research sites in Vietnam and sending the report to the Evaluation Board on Ethics Issues in Biomedical Research of the Ministry of Health, Institutional Ethics Committee of the trial site/main site;

Updating the information about unexpected ADR of the investigational products at the research sites to inform the investigators and supplement into Dossier of investigational product;

Summarising the data on adverse events, serious adverse events to introduce them into annual periodical progress report and summary report of research result.

e) *Evaluation Board on Ethics Issues in Biomedical Research of the Ministry of Health:* Being responsible for considering, evaluating the received SAE reports, organising the supervision, checking of the research site in necessary cases and consulting with the management authority in order to have timely direction for Investigator, Trial Sites, Sponsor aimed at ensuring the absolute safety for the research subject.

f) *National ADR Centre:* is responsible for coordinating with Evaluation Board on Ethics Issues in Biomedical Research of the Ministry of Health to analyze, conduct statistic for all reported SAE in clinical trial.

4. Procedure, time frame and form for SAE report

For all SAEs: Principal investigator is responsible for reporting urgently to the Sponsor and Institutional Ethics Committee of the Testing Organisation within 24 hours from learning of the event. Depending on each type of SAE, reporting to the Evaluation Board on Ethics Issues in Biomedical Research of the Ministry of Health and to related organisations as follows:

a) *For fatal or life-threatening SAEs*: principal investigator coordinates with Sponsor to complete the information and send the report to the Evaluation Board on Ethics Issues in Biomedical Research of the Ministry of Health. **The initial report** must be done in writing, as early as possible but not later than 7 days from the date of receiving the SAE information. The content of the initial report is according to the report form (Appendix 1) but it is not necessary to have sufficient information at the time of reporting. **The follow-up report** with all sufficient details of the report form (Appendix 1) to be completed and sent within 15 days from the time of receiving the SAE information.

b) *For other SAEs that are not fatal or life-threatening*: The principal investigator coordinates with the Sponsor to complete the information and sends the detailed SAE report (Appendix 1) to the Evaluation Board on Ethics Issues in

Biomedical Research of the Ministry of Health as early as possible but not later than 15 days from the date of receiving the SAE information.

APPENDIX 1

SERIOUS ADVERSE EVENT REPORT FORM

Protocol ID: **Principal Investigator:**

Name of study:

Study sponsor:

Study site:

Serious adverse event (SAE) report: ☐ **Initial report**

REPORT ID…….. ☐ **Updated follow-up report (… times)**

☐ **Final report**

I. Information about subject having SAE

1. Research subject ID	2. Abbreviated name:	3. Sex	4. Age

II. Information about investigational product

1. Name of investigational product (*generic name INN, trade name, manufacturer*)
2. Lot number of investigational product: …….. Manufacturing date: …… Expiry date: …….
3. Indication:
4. Dosage and route of administration:
5. Starting date and time of day:
6. Stopping date and time (or duration of using the investigational product):
7. How many doses have been used (for vaccine):

III. Information about the SAE

1. Name of SAE: ……..
2. Location where SAE was acknowledged (which research site?): …….
3. Description of the SAE (*detailed description about the SAE*)

Date and time of onset of SAE

……...

Development of SAE: signs, clinical symptoms: ……..

……...……...

……...……...

……...……...

……...……...

Laboratory test

……...……...

……...……...

……...……...

The reason/s why the investigator indentified this as an SAE:

……...……...

Relation level between the SAE and the investigational product (according to the consideration of the investigator):

☐ *Definitely related*

☐ *Having many possibilities of being related*

☐ *Possibly related*

☐ *Having few possibilities of being related*

☐ *Not related*

4. This SAE is:

   ☐ Expected

   ☐ Unexpected

   (Have the nature, frequency and severity of adverse event as described in investigational product/medical materials ever been observed?)

   Yes → Expected *No → Unexpected*

5. Severity of the SAE:

   ☐ Fatal

   ☐ Life threatening

   ☐ Not fatal or life-threatening (please specify) ……..

6. How many similar SAEs have happened at the research site (in this research, calculation at the time of reporting) ……..

IV. Information about the SAE treatment/settlement

1. Concomitant medicinal products before onset of SAE ……

   ……...

   ……...

   ……...

2. Medicines, medical interventions which were settled for the research subject having the SAE (Please specify in details)

   ……...

   ……...

3. Status of subject having the SAE at the reporting time

   ☐ Not yet recovered ☐ Recovered with sequelae ☐ Fatal

   ☐ Recovering ☐ Recovered without sequelae ☐ Unknown

……

V. Professional opinion of the Ethics Committee/Scientific Committee of the Research Site

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Proposal

For subject having the SAE ☐ Continue with research ☐ Suspend ☐ Withdraw from research

For the research ☐ Continue to deploy ☐ Suspend research ☐ Stop research

VI. Proposal of the principal investigator

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Date of report ……..

Reported by (sign, state full name, qualification) ……

Leader of research site (sign, state full name)